

## **TITLE 22. EXAMINING BOARDS**

### **Part 15. Texas State Board of Pharmacy**

#### **Chapter 291. Pharmacies**

##### **Subchapter C. Nuclear Pharmacy (Class B)**

#### **22 TAC §291.52, §291.53, §291.54, §291.55**

The Texas State Board of Pharmacy proposes amendments to §291.52 concerning Definitions, §291.53 concerning Personnel, §291.54 concerning Operational Standards, and §291.55 concerning Records in a Class B (Nuclear) Pharmacy. The amendments to §§291.52-291.54, if adopted, will amend the current provisions relating to compounding of sterile pharmaceuticals to match new section §291.26 which outlines new provisions for the compounding of sterile pharmaceuticals. The amendments to §291.55, if adopted, will specify that only a pharmacist may verify the receipt of controlled substances by a pharmacy.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be no fiscal implications for state government as a result of enforcing or administering the rule. There are no anticipated fiscal implications for local government.

Ms. Dodson has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the rule will be the establishing of standards for the compounding of non-sterile and sterile pharmaceuticals by pharmacies and stricter controls on the receipt of controlled substances by pharmacies. There is no fiscal impact anticipated for small or large businesses or to other entities who are required to comply with this section.

A public hearing to receive comments on the proposed amendments will be held at 9:00 a.m. on Tuesday, November 18, 2003, at the Health Professions Council Board Room, 333 Guadalupe Street, Tower II, Room 2-225, Austin, Texas 78701. Persons planning to present comments to the Board are asked to provide a written copy of their comments prior to the hearing or bring 20 copies to the hearing. Written comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, 333 Guadalupe Street, Suite 3-600, Austin, Texas, 78701, FAX: 512/305-8082, E-mail: allison.benz@tsbp.state.tx.us. Comments must be received by 5 p.m., November 12, 2003.

The amendments are proposed under sections 551.002 and 554.051(a) of the Texas Pharmacy Act (Chapters 551-566 and 568-569, Texas Occupations Code). The Board interprets section 551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets section 554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by this rule: Chapters 551-566 and 568-569, Texas Occupations Code.

The agency hereby certifies that the proposed amendments have been reviewed by legal counsel and found to be a valid exercise of the agency's authority.

#### **§291.52 Definitions**

The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set forth in the Act, §551.003.

(1) - (3) (No Change.)

(4) Airborne particulate cleanliness class - The level of cleanliness specified by the maximum allowable number of particles per cubic foot of air as specified in Federal Standard 209E, et seq. For example:

(A) Class 100 (**ISO Class 5**) is an atmospheric environment which contains less than 100 particles no greater than 0.5 microns in diameter per cubic foot of air;

(B) Class 10,000 (**ISO Class 7**) is an atmospheric environment which contains less than 10,000 particles no greater than 0.5 microns in diameter per cubic foot of air; and

(C) Class 100,000 **(ISO Class 8)** is an atmospheric environment which contains less than 100,000 particles no greater than 0.5 microns in diameter per cubic foot of air.

**(5) Ancillary supplies - Supplies necessary for the administration of compounded sterile pharmaceuticals.**

**(6) Aseptic preparation - The technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.**

**(7) [(5)] Authentication of product history - Identifying the purchasing source, the intermediate handling, and the ultimate disposition of any component of a radioactive drug.**

**(8) [(6)] Authorized nuclear pharmacist - A pharmacist who has completed the specialized training requirements specified by these rules for the preparation and distribution of radiopharmaceuticals.**

**(9) [(7)] Authorized user - Any individual named on a Texas radioactive material license, issued by the Texas Department of Health, Bureau of Radiation Control.**

**(10) [(8)] Automated compounding or drug dispensing device - An automated device that compounds, measures, counts, packages, and/or labels a specified quantity of dosage units for a designated drug product.**

**(11) [(9)] Biological Safety Cabinet - Containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49.**

**(12) [(10)] Board - The Texas State Board of Pharmacy.**

**(13) [(11)] Certified Pharmacy Technician - A pharmacy technician who:**  
(A) - (C) (No Change.)

**(14) [(12)] Class B pharmacy license or nuclear pharmacy license - A license issued to a pharmacy dispensing or providing radioactive drugs or devices for administration to an ultimate user.**

**(15) [(13)] Clean room - A room in which the concentration of airborne particles is controlled and there are one or more clean zones according to Federal Standard 209E, et seq.**

**(16) [(14)] Clean zone - A defined space in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class.**

**(17) Component - Any ingredient intended for use in the compounding of a drug product, including those that may not appear in such product.**

**(18) Compounding - The preparation, mixing, assembling, packaging, or labeling of a drug or device:**

**(A) as the result of a practitioner's prescription drug or medication order or initiative based on the practitioner-patient pharmacist relationship in the course of professional practice;**

**(B) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or**

**(C) for the purpose of or as an incident to research, teaching, or chemical analysis and not for sale or dispensing.**

**(19) [(15)] Controlled area - A controlled area is the area designated for preparing sterile radiopharmaceuticals.**

**(20) [(16)] Controlled substance - A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1-4 of the Texas Controlled Substances Act, as amended, or a drug, immediate precursor, or other substance included in Schedule I, II, III, IV, or V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).**

**(21) Critical site - Any opening providing a direct pathway between a sterile product and the environment or any surface coming in direct contact with the product and the environment.**

**(22) [(17)] Dangerous drug - A device, drug, or radioactive drug that is unsafe for self medication and that is not included in Penalty Groups I through IV of Chapter 481 (Texas Controlled Substances Act). The term includes a device, drug, or radiopharmaceutical that bears or is required to bear the legend:**

(A) -(B) (No Change.)

**(23) [(18)] Data communication device - An electronic device that receives electronic information from one source and transmits or routes it to another (e.g., bridge, router, switch, or**

gateway).

**(24)** ~~[(19)]~~ Deliver or delivery - The actual, constructive, or attempted transfer of a prescription drug or device, radiopharmaceutical, or controlled substance from one person to another, whether or not for a consideration.

**(25)** ~~[(20)]~~ Designated agent -  
(A) - (B) (No Change.)

**(26)** ~~[(21)]~~ Device - An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related articles, including any component parts or accessory that is required under federal or state law to be ordered or prescribed by a practitioner.

**(27)** ~~[(22)]~~ Diagnostic prescription drug order - A radioactive prescription drug order issued for a diagnostic purpose.

**(28)** ~~[(23)]~~ Dispense - Preparing, packaging, compounding, or labeling for delivery a prescription drug or device, or a radiopharmaceutical in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

**(29)** ~~[(24)]~~ Dispensing pharmacist - The authorized nuclear pharmacist responsible for the final check of the dispensed prescription before delivery to the patient.

**(30)** ~~[(25)]~~ Distribute - The delivering of a prescription drug or device, or a radiopharmaceutical other than by administering or dispensing.

**(31)** ~~[(26)]~~ Electronic radioactive prescription drug order - A radioactive prescription drug order which is transmitted by an electronic device to the receiver (pharmacy).

**(32)** ~~[(27)]~~ Internal test assessment - Validation of tests for quality control necessary to insure the integrity of the test.

**(33)** ~~[(28)]~~ Nuclear pharmacy technique - The mechanical ability required to perform the nonjudgmental, technical aspects of preparing and dispensing radiopharmaceuticals.

**(34)** ~~[(29)]~~ Original prescription - The:  
(A) - (B) (No Change.)

**(35)** ~~[(30)]~~ Pharmacist-in-charge - The pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

**(36)** ~~[(31)]~~ Pharmacy technician - Those individuals utilized in pharmacies whose responsibility it shall be to provide technical services that do not require professional judgment concerned with the preparation and distribution of drugs or radiopharmaceuticals under the direct supervision of and responsible to a pharmacist. Pharmacy technician includes certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees.

**(37)** ~~[(32)]~~ Pharmacy technician trainee - A pharmacy technician:  
(A) - (B) (No Change.)

**(38)** ~~[(33)]~~ Process validation - Documented evidence providing a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

**(39)** **Quality assurance - The set of activities used to assure that the process used in the preparation of sterile drug products lead to products that meet predetermined standards of quality.**

**(40)** ~~[(34)]~~ Radiopharmaceutical - A prescription drug or device that exhibits spontaneous disintegration of unstable nuclei with the emission of a nuclear particle(s) or photon(s), including any nonradioactive reagent kit or nuclide generator that is intended to be used in preparation of any such substance.

**(41)** ~~[(35)]~~ Radioactive drug quality control - The set of testing activities used to determine that the ingredients, components (e.g., containers), and final radiopharmaceutical prepared meets predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility and the interpretation of the resulting data in order to determine the feasibility for use in humans and animals including internal test assessment, authentication of product history, and the keeping of mandatory records.

**(42)** ~~[(36)]~~ Radioactive drug service - The act of distributing radiopharmaceuticals; the participation in radiopharmaceutical selection and the performance of radiopharmaceutical drug reviews.

**(43)** ~~[(37)]~~ Radioactive prescription drug order - An order from a practitioner or a practitioner's

designated agent for a radiopharmaceutical to be dispensed.

**(44)** ~~[(38)]~~ Sterile radiopharmaceutical - A dosage form of a radiopharmaceutical free from living micro-organisms.

**(45)** ~~[(39)]~~ Therapeutic prescription drug order - A radioactive prescription drug order issued for a specific patient for a therapeutic purpose.

**(46)** ~~[(40)]~~ Ultimate user - A person who has obtained and possesses a prescription drug or radiopharmaceutical for his or her own use or for the use of a member of his or her household.

### **§291.53 Personnel**

(a) Pharmacists-in-Charge.

(1) (No Change.)

(2) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum, the following:

(A) - (B) (No Change.)

**(C) determining that all pharmacists involved in compounding sterile radiopharmaceuticals obtain continuing education appropriate for the type of compounding done by the pharmacist;**

**(D) ~~[(C)]~~ supervising a system to assure appropriate** ~~[establishing policies for]~~ procurement of drugs and devices and storage of all pharmaceutical materials including radiopharmaceuticals, components used in the compounding of radiopharmaceuticals, and drug delivery devices;

**(E) assuring that the equipment used in compounding is properly maintained;**

**(F) ~~[(D)]~~ developing a system for the disposal and distribution of drugs from the Class B pharmacy;**

**(G) developing a system for bulk compounding or batch preparation of radiopharmaceuticals;**

**(H) ~~[(E)]~~ developing a system for the compounding, sterility assurance, and quality control of sterile radiopharmaceuticals;**

**(I) ~~[(F)]~~ maintaining records of all transactions of the Class B pharmacy necessary to maintain accurate control over and accountability for all pharmaceutical materials including radiopharmaceuticals, required by applicable state and federal laws and rules;**

**(J) ~~[(G)]~~ developing a system to assure the maintenance of effective controls against the theft or diversion of prescription drugs, and records for such drugs;**

**(K) ~~[(H)]~~ assuring that the pharmacy has a system to dispose of radioactive and cytotoxic waste in a manner so as not to endanger the public health; and**

**(L) ~~[(I)]~~ legal operation of the pharmacy, including meeting all inspection and other requirements of all state and federal laws or rules governing the practice of pharmacy.**

(b) Authorized nuclear pharmacists.

(1) General.

(A) - (F) (No Change.)

(2) **Special requirements for sterile compounding.**

**(A) All pharmacists engaged in compounding shall:**

**(i) possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised; and**

**(ii) obtain continuing education appropriate for the type of compounding done by the pharmacist.**

**(B) A pharmacist shall inspect and approve all components, drug product containers, closures, labeling, and any other materials involved in the compounding process.**

**(C) A pharmacist shall review all compounding records for accuracy and conduct in-process and final checks to assure that errors have not occurred in the compounding process.**

**(D) A pharmacist is responsible for the proper maintenance, cleanliness, and use of all equipment used in the compounding process.**

**(3) Duties.** Duties which may only be performed by an authorized nuclear pharmacist are as follows:

(A) - (E) (No Change.)

(c) Pharmacy Technicians.

(1) General.

(A) - (G) (No Change.)

(2) **Special requirements for sterile compounding. Pharmacy technicians may compound sterile pharmaceuticals provided the pharmacy technicians:**

**(A) are either certified pharmacy technicians or technician trainees;**

**(B) have completed the education and training specified in paragraph (4) of this subsection; and**

**(C) are supervised by a pharmacist who has completed the training specified in paragraph (4) of this subsection, conducts in-process and final checks, and affixes his or her initials to the appropriate quality control records.**

**(3) Duties.**

(A) - (B) (No Change.)

**(4) [(3)] Ratio of authorized nuclear pharmacist to pharmacy technicians.**

(A) - (B) (No Change.)

(d) Special education, training, and evaluation requirements for pharmacy personnel compounding or responsible for the direct supervision of pharmacy personnel compounding sterile radiopharmaceuticals.

(1) (No Change.)

(2) Pharmacists.

(A) All pharmacists who compound sterile radiopharmaceuticals or supervise pharmacy technicians compounding sterile radiopharmaceuticals shall:

(i) **initially and every seven years thereafter, [effective January 1, 2000,] complete through a single course, a minimum of [a recognized course in an accredited college of pharmacy or a course sponsored by an American Council on Pharmaceutical Education approved provider which provides] 20 hours of instruction and experience in the areas listed in §291.26(c)(4) of this title (relating to Pharmacies Compounding Sterile Pharmaceuticals). Such training may be obtained through:**

**(I) completion of a structured on-the-job didactic and experiential training program at this pharmacy which provides 20 hours of instruction and experience in the areas listed in §291.26(c)(4) of this title. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; or**

**(II) completion of a recognized course in an accredited college of pharmacy or a course sponsored by an American Council on Pharmaceutical Education approved provider which provides 20 hours of instruction and experience in the areas listed in §291.26(c)(4) of this title; [paragraph (1) of this subsection;] and**

(ii) possess knowledge about:

(I) aseptic processing;

(II) quality control **and quality assurance** as related to environmental, component, and end-product testing;

(III) chemical, pharmaceutical, and clinical properties of drugs;

(IV) container, equipment, and closure system selection; and

(V) sterilization techniques.

~~[(B) — Pharmacists shall discontinue preparation of sterile radiopharmaceuticals if the training specified in subparagraph (A) of this paragraph is not completed by January 1, 2000.]~~

**(B) [(C)] The required experiential portion of the training programs specified in this paragraph must be supervised by an individual who has already completed training in the compounding of sterile pharmaceuticals as specified in §291.26(c)(4) of this title.**

(3) Pharmacy technicians. In addition to the qualifications and training outlined in subsection (c) of this section, all pharmacy technicians who compound sterile radiopharmaceuticals shall:

(A) (No Change.)

**(B) have initial training obtained either through completion of:**

**(i) a single course, a minimum of 40 hours of instruction and experience in the areas listed in §291.26(c)(4) of this title. Such training may be obtained through:**

(I) completion of a structured on-the-job didactic and experiential training program at this pharmacy which provides 40 hours of instruction and experience in the areas listed in §291.26(c)(4) of this title. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; or

(II) completion of a course sponsored by an ACPE approved provider which provides 40 hours of instruction and experience in the areas listed in §291.26(c)(4) of this title; or

(ii) a training program which is accredited by the American Society of Health-System Pharmacists (formerly the American Society of Hospital Pharmacists). Individuals enrolled in training programs accredited by the American Society of Health-System Pharmacists may compound sterile pharmaceuticals in a licensed pharmacy provided:

(I) the compounding occurs only during times the individual is assigned to a pharmacy as a part of the experiential component of the American Society of Health-System Pharmacists training program;

(II) the individual is under the direct supervision of and responsible to a pharmacist who has completed training as specified in §291.26(c)(4) of this title; and

(III) the supervising pharmacist conducts in-process and final checks; and

(C) repeat the training specified in subparagraph (B) of this paragraph at least every seven years; and

(D) acquire the required experiential portion of the training programs specified in this subparagraph under the supervision of an individual who has already completed training as specified in paragraph (1) or (3) of this subsection. [complete through a single course, a structured on-the-job didactic and experiential training program at this pharmacy which provides 40 hours of instruction and experience in the areas listed in paragraph (1) of this subsection. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program;

~~(C) — acquire the required experiential portion of the training programs specified in this paragraph under the supervision of an individual who has already completed training in the compounding of sterile pharmaceuticals.~~

~~(E) [(D) effective January 1, 2001,] be certified pharmacy technicians.~~

~~[(E) — on January 1, 2001, discontinue preparation of sterile pharmaceuticals if the technician has not taken and passed the National Pharmacy Technician Certification Exam or other examination approved during an open meeting by the Board. Such pharmacy technicians may continue to compound sterile pharmaceuticals during the interim between the effective date of these rules and January 1, 2001, if they maintain documentation of completion of the training specified in subparagraph (B) of this paragraph.]~~

(4) (No Change.)

#### **§291.54 Operational Standards**

(a) Licensing requirements.

(1) -(9) (No Change.)

(10) A Class B pharmacy, licensed under the provisions of the Act, §560.051(a)(2), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class A), is not required to secure a license for such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of §291.31 of this title (relating to Definitions); §291.32 of this title (relating to Personnel); §291.33 of this title (relating to Operational Standards); §291.34 of this title (relating to Records); **and** §291.35 of this title (relating to **Official** [Triplicate] Prescription Requirements); ~~and §291.36 of this title (relating to Class A Pharmacies [Dispensing Compounded Sterile Parenteral and/or Enteral Products], contained in Community Pharmacy (Class A)), to the extent such rules are applicable to the operation of the pharmacy.~~

(11) A Class B pharmacy engaged in nonsterile compounding of drug products shall comply with the provisions of **§291.25 of this title (relating to Pharmacies Compounding Non-Sterile**

**Pharmaceuticals)** [§§291.31 – 291.34 of this title (relating to Definitions, Personnel, Operational Standards, and Records for Class A (Community) Pharmacies) to the extent such rules are applicable to nonsterile compounding of drug products.]

**(12) A Class B pharmacy engaged in sterile compounding of pharmaceutical drug products other than radiopharmaceuticals shall comply with the provisions of §291.26 of this title (relating to Pharmacies Compounding Sterile Pharmaceuticals.**

(b) Environment.

(1) (No Change.)

(2) Special requirements for the compounding of sterile radiopharmaceuticals. When the pharmacy compounds sterile radiopharmaceuticals, the following is applicable.

(A) (No Change.)

(B) Controlled area. The pharmacy shall have a designated controlled area for the compounding of sterile radiopharmaceuticals that is functionally separate from areas for the preparation of non-sterile pharmaceuticals and is constructed to minimize the opportunities for particulate and microbial contamination. **This controlled area for the preparation of sterile pharmaceuticals shall:**

**(i) have a controlled environment that is aseptic or contains an aseptic environmental control device(s). If the aseptic environmental control device is located within the controlled area, the controlled area must extend a minimum of six feet from the device and clearly marked to identify the separation between the controlled and non-controlled area;**

**(ii) be clean, well lighted, and of sufficient size to support sterile compounding activities;**

**(iii) be used only for the compounding of sterile pharmaceuticals;**

**(iv) be designed to avoid outside traffic and air flow;**

**(v) be designed such that hand sanitizing and gowning occurs outside the controlled area but accessible without use of the hands of the compounding personnel;**

**(vi) have non-porous and washable floors or floor covering to enable regular disinfection;**

**(vii) be ventilated in a manner not interfering with aseptic environmental control conditions;**

**(viii) have hard cleanable walls and ceilings (acoustical ceiling tiles that are coated with an acrylic paint are acceptable);**

**(ix) have drugs and supplies stored on shelving areas above the floor to permit adequate floor cleaning; and**

**(x) contain only the appropriate compounding supplies and not be used for bulk storage for supplies and materials.**

(C) (No Change.)

(3) (No Change.)

(c) - (d) (No Change.)

(e) Equipment. The following minimum equipment is required in a nuclear pharmacy:

(1) vertical laminar flow hood;

(2) dose calibrator;

**(3) refrigerator and a system or device (i.e., thermometer) to monitor the temperature daily to ensure that proper storage requirements are met if sterile pharmaceuticals are stored in the refrigerator;**

**(4) Class A prescription balance, and accurate weights or balance of greater sensitivity if compounding occurs in the pharmacy which requires weighing;**

**(5) scintillation analyzer;**

**(6) microscope and hemocytometer;**

**(7) equipment and utensils necessary for the proper compounding of prescription drug or medication orders. Such equipment and utensils used in the compounding process shall be:**

**(i) of appropriate design, appropriate capacity, and be operated within designed operational limits;**

**(ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond acceptable**

standards;

(iii) cleaned and sanitized immediately prior to each use; and

(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper

performance;

(8) appropriate disposal containers for used needles, syringes, etc., and if applicable, cytotoxic waste from the preparation of chemotherapeutic agents, and/or biohazardous waste;

(9) all necessary supplies, including:

(i) disposable needles, syringes, and other aseptic mixing;

(ii) disinfectant cleaning solutions;

(iii) hand washing agents with bactericidal action;

(iv) disposable, lint free towels or wipes;

(v) appropriate filters and filtration equipment;

(vi) cytotoxic spill kits, if applicable; and

(vii) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves,

as applicable.

(10) [7] adequate glassware, utensils, gloves, syringe shields and remote handling devices, and adequate equipment for product quality control;

(11) [~~8~~] adequate shielding material;

(12) [~~9~~] typewriter or comparable equipment;

(13) [~~10~~] radiation dosimeters for visitors and personnel and log entry book;

(14) [~~11~~] exhaust/fume hood with monitor, for storage and handling of all volatile radioactive drugs if applicable, to be determined by the Texas Radiation Control Bureau;

(15) [~~12~~] calculator; and

(16) [~~13~~] adequate radiation monitor(s).

(f) - (i) (No Change.)

**§291.55 Records**

(a) - (c) (No Change.)

(d) Other records. Other records to be maintained by a pharmacy:

(1) - (3) (No Change.)

(4) suppliers' invoices of dangerous drugs and controlled substances; **a pharmacist** [~~pharmacists or other responsible individuals~~] shall verify that the controlled drugs listed on the invoices were actually received by clearly recording **his/her** [~~their~~] initials and the actual date of receipt of the controlled substances;

(5) - (9) (No Change.)

(e) - (f) (No Change.)